

STANDARDS: US FDA has not issued performance standards for automated perimeters.

Notal Vision, Inc.	Original 510(k)
PreView PHP™	SUMMARY STATEMENT

INDICATIONS FOR USE:

The PreView PHP™ is intended for use in the detection and monitoring the progression of Age-related Macular Degeneration (AMD) including, but not limited to, the detection of choroidal neovascularization (CNV).

SUBSTANTIAL EQUIVALENCE:

The Notal Vision Ltd. PreView Preferential Hyperacuity Perimeter (PreView PHP™) is substantially equivalent to the following combination of predicate medical devices:

- Humphrey Field Analyzer: Perimeter, Automatic, AC-Powered, a class I Exempt medical device (21 CFR 886.1605); (K954167) Product Code HPT
- Octopus 500/500e (21CFR 886.1605); (K841099) Product Code HPT.
- The Heidelberg Retina Angiograph FA/ICGA (HRA/C), (Heidelberg Engineering, Germany) cleared under K971671; Product Code HLI
- The Macular Computerized Psychophysical Test (MCPT), (Notal Vision, Inc.) cleared under K014044: Product Code HOQ
- Amsler Grid, a Class I Exempt Preamendments Medical Device (21 CFR 886.1330): Product Code HOQ

DEVICE DESCRIPTION:

The PreView PHP™ system is an interactive software driven device that provides a series of horizontal and vertical linear images to the macular and peri-macular region of the eye to detect abnormalities of the central and paracentral visual field that will detect and monitor progression of age related macular degeneration including detection of choroidal neovascularization. The changes in macular and near macular function are identified by the device thus enabling the reader to detect intermediate and advancing changes in macular degeneration and associated diseases to provide the capability for earlier intervention.

The PreView PHP™ is a specialized perimeter, and applies the concept of the static and automated perimeter in the detection of visual field defects. The device incorporates the theory of hyperacuity to address more highly specific central and paracentral visual fields. Because of hyperacuity, perception of more finite relative spatial localization. Hyperacuity is defined as the ability to perceive a difference in the relative spatial localization of points on the central field, more specific distortions or misalignments within the central and paracentral field can be mapped with greater accuracy. The device monitors and manages the progressive changes associated with advancing macular degeneration and differentiates the different stages of AMD including but not limited to choroidal neovascularization.

The PreView PHP™ system is designed for use with standard off-the-shelf PC units in the office of the practitioner. It is aimed to detect advancing changes of AMD-related lesions including but not limited to choroidal neovascularization.

CLINICAL INVESTIGATION

The purpose of the clinical investigation was to assess the ability of the Preferential Hyperacuity Perimeter (PreView PHP™) to detect the recent onset of choroidal neovascularization (CNV) due to age-related macular degeneration (AMD) and differentiate it from an intermediate stage of

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AMD. The study design was a prospective, comparative, concurrent, non-randomized multi-center study

Eligible subjects had in their study eye a corrected visual acuity of 20/160 or better as well as either untreated CNV from AMD diagnosed within the last 60 days or an intermediate stage of AMD (at least 1 large druse or at least 20 medium-size drusen) with no evidence of geographic atrophy of the retinal pigment epithelium or other macular diseases.

A successful outcome was defined *a priori* as a sensitivity of at least 80% and a specificity of at least 80%.

The results demonstrated that the sensitivity to detect recent onset of CNV was 82% (95% confidence interval [CI]: 72% to 92%). The specificity to differentiate recent onset of CNV from the intermediate stage of AMD was 88% (95% CI: 81% to 96%).

In conclusion, the PreView PHP™ testing can detect recent onset of CNV due to AMD and differentiate it from an intermediate stage of AMD with high sensitivity and specificity. These data suggest that monitoring with PHP should detect most CNV of recent onset with few false positives at a stage when treatment usually would be beneficial so that this monitoring should be considered in the management of the intermediate stage of AMD.

LABELING

The Notal Vision PreView PHP™ system is provided with a User Manual for the Practitioner. The information is available from the company:

Notal Vision, Inc.
5 Droyanov Street
Tel Aviv 63143, Israel



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 29 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Notal Vision, Inc.
c/o Richard E. Lippman, O.D., F.A.A.O.
Vice President, Ophthalmic Product Regulatory Affairs
R.P. Chiacchierini & Associates, LLC
15835 Shady Grove Road, Suite 30
Rockville, MD 20850

Re: K050350
Trade/Device Name: PreView Preferential Hyperacuity Perimeter (PreView PHP™)
Regulation Number: 21 CFR 886.1605
Regulation Name: Perimeter
Regulatory Class: Class I
Product Code: HPT
Dated: February 9, 2005
Received: February 11, 2005

Dear Dr. Lippman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, reading "David M. Whipple". The signature is fluid and cursive, with the first name "David" being the most prominent.

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

510(k) Number (if known): K050350

Device Name: The Notal Vision Preview Preferential Hyperacuity Perimeter (Preview PHP™)

Indications for Use:

The PreView Preferential Hyperacuity Perimeter (PreView PHP™) is intended for use in the detection and characterization of central and paracentral metamorphopsia (visual distortion) in patients with age-related macular degeneration, as an aid in monitoring progression of disease factors causing metamorphopsia including but not limited to choroidal neovascularization (CNV). It is intended to be used in the office of a licensed eye care practitioner in patients with stable fixation.

Additional Claims:

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

OR

Over -The-Counter Use

M.R. Nicholas

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

(Optional Format 1-2-96)

510(k) Number K050350